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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,184	09/24/2003	Tim Keith	2976-4039US3	2818

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MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/670,184	Applicant(s) KEITH ET AL.	
	Examiner Christine J. Saoud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 23, 24, 27-35, 40, 41, 44-47, 52, 53, 56, 57 and 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 26, 36-39, 42, 43, 48-51, 54, 55, 58, 59, 63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 and 23-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/24/03, 10/12/04</u> | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, further directed to the invention of antibodies which bind SEQ ID NO:5 in the reply filed on 04 January 2007 is acknowledged (Applicant referred to this as an election of species, but page 3 of the restriction clearly points out that this was an election of invention). The traversal is on the ground(s) that (1) the groups of restricted claims are properly presented in the same application, (2) undue diverse searching would not be required and (3) all claims should be examined together. This is not found persuasive because MPEP 803 provides that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search for the claimed inventions. Such was provided in the previous Office action. Applicant argues that to properly search any one group, other group classifications must be considered as well to perform a comprehensive search. Whereas this may be true, it would not constitute a complete search for the inventions of the other groups, and additional searches would need to be performed in the appropriate classifications for each invention and in the appropriate art fields (polypeptides, nucleic acids, antibodies, methods, etc). Contrary to Applicant's assertion that compositions and methods of those polypeptide and nucleic acids claims may be classified together, these compounds and compositions (for use in methods) are separately classifiable. This would constitute an undue, serious burden of search for the Examiner because the searches, although possibly "overlapping", are not co-

extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21, 23-24, 27-35, 40-41, 44-47, 52-53, 56-57, and 60-62 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04 January 2007.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 24 September 2003 and 12 October 2004 are in compliance with the provisions of 37 CFR 1.97 and have been considered by the examiner.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 2, line 8, page 7, line 15, page 41, lines 9-14, 17, 26, page 42, lines 26-27, 30, page 51, lines 11, 18, 25, page 52, lines 12, 30, page 53, lines 12, 27, 32 and page 54, line 9.

The specification is objected to for failure to comply with the Sequence rules. All nucleic acids of at least 10 nucleotides in length and all amino acid sequences of at least 4 amino acids in length must be represented by a Sequence identifier. Deficiencies are noted at page 47, page 49, line 25, pages 56-57, Table 3, pages 58-59, Table 4, page 70, line 18 and Table 7, pages 74-75, Table 8 and Table 9, page 77, Table 10, pages 85-86, Table 12. See MPEP 2422, 37 CFR 1.821(c) and (d).

The possible use of the trademarks has been noted in this application. When using a trademark, it should be capitalized wherever it appears and be accompanied by the generic terminology. There are several instances of the use of all capital letters in the specification, so it appears that these may be trademarks.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

Claim 63 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 38. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 64 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 51. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-51 and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are directed to pharmaceutical compositions, which implies the ability to use the compositions *in vivo*. The instant specification provides no evidence or examples of an antibody which would be useful for treating any particular condition. While it may be routine to make antibodies which bind a specific protein or antigenic fragment of a protein, it is not routine to make a therapeutic antibody which is useful for treatment of particular diseases and conditions. Furthermore, the instant specification has not provided a nexus between the polypeptide of SEQ ID NO:5 and

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any biological function that should be inhibited with an antibody for a therapeutic purpose. It is noted that nucleic acid encoding SEQ ID NO:5 was linked to asthma, therefore, detection of the polypeptide encoded thereby would provide a means for detecting/diagnosing a predisposition to asthma, however, this does not mean that the protein itself is necessarily involved in the disease process or that inhibition of the protein would provide a therapeutic effect. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Reasonable correlation must exist between the scope of the claims and the scope of enablement set forth. In view of the quantity of experimentation necessary, the lack of working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would require undue experimentation to practice the claimed invention.

Claims 25-26, 36-39 42-43, 58-59 and 63-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to antibodies which bind to a polypeptide "comprising the amino acid sequence of SEQ ID NO:5". However, this does not require the antibody to actually bind a portion of SEQ ID NO:5, but rather, the antibody could bind to anything that the protein is attached to. Because there is no recitation of what the "anything"

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would be, there is insufficient structure and other identifying characteristics to describe the claimed invention. The claims could potentially encompass any antibody which binds any structure that could be bound to the polypeptide of SEQ ID NO:5. Art will be applied accordingly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25-26, 36-39 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Hopp et al., U.S. Patent Number 5,011,912, April 1991.

Hopp et al. teach the use of an amino acid sequence, "ADYKDDDDK", which is disclosed as being immunogenic, for use in producing fusion proteins which can then be easily purified. See, for example, column 2, lines 45-57. Hopp et al. also teach monoclonal antibodies which bind this flag peptide. Because the claims fail to recite indicate that the antibody binds to the polypeptide of SEQ ID NO:5, the antibody could also be binding to some other portion of the polypeptide. The amino acid sequence of Hopp et al. is used universally for making fusion proteins, therefore, the claims readily

encompass such an embodiment. Therefore, the claims are anticipated by the monoclonal antibodies of Hopp et al.

Claims 25-26, 36-39, 42-4358-59 and 63-64 are rejected under 35 U.S.C. 102(e) as being anticipated by US2003/0027275 (Baker et al.).

Baker et al. teach a polypeptide which is 99.5% identical to the polypeptide of SEQ ID NO:5 (see SEQ ID NO:466). Baker et al. also disclose antibodies (see page 57 at [0795]) including monoclonals ([0796]) and fragments ([0814]). Pharmaceutical compositions are disclosed at page 61 and immobilization on a solid support is disclosed at ([0830]). Therefore, the invention is anticipated by the prior art of Baker et al.

Conclusion

No claim is allowed.

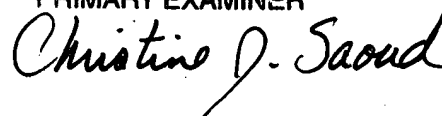
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Christine J. Saoud". The signature is written in a cursive, flowing style.

<!--StartFragment-->RESULT 2

US-10-176-918-466

; Sequence 466, Application US/10176918

; Publication No. US20030027275A1

; GENERAL INFORMATION:

; APPLICANT: Baker, Kevin P.

; APPLICANT: Chen, Jian

; APPLICANT: Desnoyers, Luc

; APPLICANT: Goddard, Audrey

; APPLICANT: Godowski, Paul J.

; APPLICANT: Gurney, Austin L.

; APPLICANT: Pan, James

; APPLICANT: Smith, Victoria

; APPLICANT: Watanabe, Colin K.

; APPLICANT: Wood, William I.

; APPLICANT: Zhang, Zemin

; TITLE OF INVENTION: SECRETED AND TRANSMEMBRANE POLYPEPTIDES AND NUCLEIC

; TITLE OF INVENTION: ACIDS ENCODING THE SAME

; FILE REFERENCE: P3430R1C82

; CURRENT APPLICATION NUMBER: US/10/176,918

; CURRENT FILING DATE: 2002-06-20

; PRIOR APPLICATION NUMBER: 10/052586

; PRIOR FILING DATE: 2002-01-15

; PRIOR APPLICATION NUMBER: 60/059263

; PRIOR FILING DATE: 1997-09-18

; PRIOR APPLICATION NUMBER: 60/059266

; PRIOR FILING DATE: 1997-09-18

; PRIOR APPLICATION NUMBER: 60/062250

; PRIOR FILING DATE: 1997-10-17

; PRIOR APPLICATION NUMBER: 60/063120

; PRIOR FILING DATE: 1997-10-24

; PRIOR APPLICATION NUMBER: 60/063121

; PRIOR FILING DATE: 1997-10-24

; PRIOR APPLICATION NUMBER: 60/063486

; PRIOR FILING DATE: 1997-10-21

; PRIOR APPLICATION NUMBER: 60/063540

; PRIOR FILING DATE: 1997-10-28

; PRIOR APPLICATION NUMBER: 60/063541

; PRIOR FILING DATE: 1997-10-28

; PRIOR APPLICATION NUMBER: 60/063544

; PRIOR FILING DATE: 1997-10-28

; Remaining Prior Application data removed - See File Wrapper or PALM.

; NUMBER OF SEQ ID NOS: 612

; SEQ ID NO 466

; LENGTH: 813

; TYPE: PRT

; ORGANISM: Homo Sapien

US-10-176-918-466

Query Match 99.5%; Score 4390; DB 6; Length 813;

Best Local Similarity 96.8%; Pred. No. 0;

Matches 787; Conservative 0; Mismatches 0; Indels 26; Gaps 1;

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